

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

IN RE: WOLF, Fred R. et al.)	
)	APPEAL NO. _____
SERIAL NO: 10/606,877)	
)	
FOR: METHOD OF IMPROVING)	
ANIMAL TISSUE QUALITY BY)	
SUPPLEMENTING THE ANIMAL)	
DIET WITH MIXED TOCOTRIENOLS)	
)	
)	BRIEF ON APPEAL
FILED: June 25, 2003)	
)	
GROUP ART UNIT: 1615)	
)	
CONFIRMATION NO: 5242)	
)	

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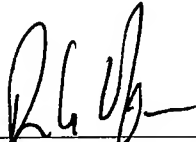
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I. INTRODUCTION

This is an appeal of the Final Rejection dated January 06, 2009, finally rejecting claims 1, 2, 12-16, 20-21 and 27-29. The appealed claims 1, 2, 12-16, 20-21 and 27-29 are set forth in the attached Claim Appendix.

II. REAL PARTY OF INTEREST

The real parties of interest for this application are Pioneer Hi-Bred International, Inc. and E.I. Du Pont De Nemours and Co., the Assignees of record for this application. The assignments have been recorded at Reel 014240 and Frame 0973 on June 25, 2003; at Reel 014239 and Frame 0702 on June 25, 2003; and at Reel 018324 and Frame 0482 on September 29, 2006.

III. RELATED APPEALS AND INTERFERENCES

None.

IV. STATUS OF CLAIMS

Claims 1-32 were originally submitted June 25, 2003. In a Response to Office Action (Restriction Requirement) dated September 1, 2006, Appellants elected Groups V (claims 12 and 13) and VI (claims 14-16 and 27-29). Rejoinder of Groups V and VI was approved in an Interview Summary mailed August 22, 2006. In an amendment dated January 19, 2007, Appellants canceled claims 3-11, 17-19, 22-26 and 30-32 as drawn to non-elected inventions.

A final rejection was mailed April 06, 2007. A Notice of Appeal was filed July 2, 2007 and an Appeal Brief was filed August 31, 2007. On March 21, 2008, an Office Action was mailed removing the finality of the claim rejections. A final rejection mailed January 06, 2009 rejected claims 1, 2, 12-16, 20, 21 and 27-29 as anticipated under 35 U.S.C. § 102(e) by Eenennaam, et al., U.S. Patent Publication No. 2003/0154513; provisionally rejected claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29 on the ground of nonstatutory obviousness-type double patenting over claims 1-27 of copending Application No. 11/153,463; and provisionally rejected claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29 on the ground of nonstatutory obviousness-type double patenting over claims 1-20 of copending Application No. 11/530,075. On February 23, 2009 Appellants filed a Response to the Final Office Action indicating that Appellants may consider terminal disclaimers upon notification of allowable subject matter in response to the provisional rejection of claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29 on the ground of nonstatutory obviousness-type double patenting over claims 1-27 of copending Application No. 11/153,463 The claims here appealed are claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29 and over claims 1-20 of copending Application No. 11/530,075. On March 29, 2009 an Advisory Action was mailed maintaining the rejection of claims 1, 2, 12-16, 20, 21 and 27-29 as anticipated under 35 U.S.C. § 102(e) by Eenennaam, et al., U.S. Patent Publication No. 2003/0154513. The claims here appealed are claims 1, 2, 12, 13, 14-16, 20, 21 and 27-29.

V. STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed on February 23, 2009, following the Examiner's Final Rejection of January 6, 2009. A Notice of Appeal was timely filed on March 23, 2009.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent claim 1

Independent claim 1 relates to a method for improving the tissue quality of an animal. (see, e.g., specification pp. 1-2, paragraphs [0017] – [0024]. The method comprises feeding the animal a diet comprising at least 150 ppm mixed tocotrienols. (Specification pp 1-2, paragraph [0018]; Specification, Examples 1-4, pp. 2-8, paragraphs [0025] – [70]).

The mixed tocotrienols may be any mixture which contains at least three of the four known tocotrienols, which are alpha-, beta-, gamma-, and delta-tocotrienol. (Specification p. 2, paragraph [0021]; p. 1, paragraph [0011]). Tissue quality is measured by a number of criteria, including pH, color value, oxidative stability, and purge loss. (Specification p. 3, paragraph [0020]). Furthermore, the diet may comprise a cereal grain crop genetically modified to have elevated mixed tocotrienol levels or oil from plant genetically modified to have elevated mixed tocotrienol levels. (Specification, p. 1, paragraph [0017]).

B. Independent claim 20

Independent claim 20 relates to a method for improving the tissue quality of an animal. See, e.g., specification pp. 1-2, paragraphs [0017] – [0024]. The method comprises

feeding the animal a diet comprising 50 ppm to 500 ppm mixed tocotrienols. Specification pp. 1-2, paragraph [0018]; Specification, Examples 1-4, pp. 2-8, paragraphs [0025] – [70].

VII. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 2, 13, 14-16, 20, 21 and 27-29 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2003/0154513 to Eenennaam, et al.

VIII. ARGUMENT

A. **Claims 1, 2, 13, 14-16, 20, 21 and 27-29 are not anticipated with respect to U.S. Patent No. 6,977,269 to U.S. Patent Publication No. 2003/0154513 to Eenennaam, et al.**

1. Legal Standard for Anticipation and Inherency

A claim may be anticipated "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). An Examiner is required to provide rationale or evidence to demonstrate and justify an inherency-based rejection. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990) ("In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.") (emphasis added). This initial burden explicitly requires an Examiner to provide extrinsic evidence making clear that the missing descriptive matter is necessarily present in the prior art and

would be so recognized by persons of ordinary skill in the art. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Therefore, the mere fact that a certain result or characteristic may be present in a prior art reference is insufficient to establish inherency. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (emphasis added).

Accordingly, extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (emphasis added). Inherency may not be established by mere probabilities or possibilities. *See, e.g., Crown Operations Intl. v. Solutia*, 289 F.3d 1367 (Fed. Cir. 2002).

2. Eenennaam, et al., either expressly or inherently, does not teach "feeding the animal a diet comprising at least 150 ppm mixed tocotrienols" or "feeding the animal a diet comprising 50 ppm to 500 ppm mixed tocotrienols"

The Examiner has not provided a reference which, expressly or inherently, contains each of the limitations present in independent claims 1 and 20 and should therefore be reversed. Eenennaam et al. may not be properly interpreted as disclosing the step of "feeding the animal a diet comprising at least 150 ppm mixed tocotrienols" in the context of independent claim 1. Moreover, Eenennaam et al. may not be properly interpreted as disclosing the step of "feeding the animal a diet comprising 50 ppm to 500 ppm mixed tocotrienols" in the context of independent claim 20. Further, Eenennaam does not disclose

the limitations of obtaining the improved tissue quality from the diet of mixed tocotrienols and identifying Applicants' precise concentrations of mixed tocotrienols.

Contrary to the Examiner's suggestions, Eenennaam *et al.* does not disclose feeding an animal a diet of mixed tocotrienols, as required by independent claims 1 and 20. The present invention teaches a diet fed to animals which requires a mixture of at least three of the four tocotrienols (α , γ , σ , and β -tocotrienols). To the contrary, Eenennaam *et al.* discloses an embodiment of increasing throughout a plant--not an animal -- levels of tocopherols and tocotrienols. (Eenennaam *et al.* [0222]). The Examiner states that Eenennaam states that "[a]ny of the plants or parts thereof of the present invention may be processed to produce a feed, meal, protein, or oil preparation". However, Eenennaam *et al.* still does not disclose the actual steps as required by independent claims 1 and 20 of administration to animals and improvement of animal tissue quality.

Further, Eenennaam *et al.* does not disclose administration of mixed tocotrienols to an animal in the ranges specified by Appellants' claims. The Examiner does not dispute this point and instead asserts that the specifically claimed concentrations of mixed tocotrienols of Applicants' claims (*i.e.*, ranges from 50 ppm to 500 ppm tocotrienol concentration) are an inherent feature of corn oil. The Examiner has not show any basis in fact or technical reasoning why the alleged range of tocotrienols in corn oil would necessarily be present in the genetically modified plants of Eenennaam *et al.* As stated above, extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental*

Can Co. USA, 948 F.2d at 1268 (Fed. Cir. 1991). Appellants have defined their invention within the precise ranges necessary for the improvement of animal tissue quality, clearly identifying the metes and bounds of their invention. To the contrary, Examiner merely suggests all inventive features are inherent, without the showing of any evidence with supporting rationale. The fact that a missing element, in this case the range of mixed tocotrienols, may be present or is possible to be present is not enough to prove that the missing element is inherent. Inherency may not be established by mere probabilities or possibilities. *See, e.g., Crown Operations Intl. v. Solutia*, 289 F.3d 1367 (Fed. Cir. 2002). Eenennaam et al. therefore does not disclose feeding an animal a diet of mixed tocotrienols in the ranges from 50 ppm to 500 ppm tocotrienol concentration, as required by independent claims 1 and 20.

Moreover, independent claims 1 and 20 both require "mixed tocotrienols". "Mixed tocotrienols" is defined in the specification as "any mixture that contains at least three of the four known tocotrienols" (α , γ , σ , and β -tocotrienols) and "any mixture of tocotrienols comprising significant quantities of at least three of the four known tocotrienols". Specification, p. 1, paragraphs [0018], [0021] (emphasis added). Eenennaam et al. does not teach improving the tissue quality of an animal comprising feeding the animal a diet of mixed tocotrienols.

The Examiner cites to paragraph 0222 of Eenennaam as disclosing elevated levels of α , γ , δ , and β -tocotrienols. Nowhere in Eenennaam et al. is there taught an animal diet or transgenic plant which comprises mixed tocotrienols as defined by Applicants' specification.

Eenennaam et al. does not present any evidence or data that the transgenic plants disclosed therein contain elevated levels of mixed tocotrienols.

Eenennaam et al. discloses data showing elevated levels of tocopherols in the disclosed transgenic plants, but no data or teaching of transgenic plants with elevated levels of mixed tocotrienols. *See, e.g.* Eenennaam et al., Table 5, pp. 33-34 (disclosing plants with altered levels of gamma-tocopherol); Example 4, pp. 36-37; FIG. 34 (comparing the gamma-tocopherol and gamma-tocotrienol levels in plants); Example 7, pp. 39-40 (discussing the tocopherol levels of transformed plants); Examples 8-9 (disclosing the measurement of alpha-, gamma-, and delta-tocopherol levels in transformed plants). The Examiner states that Eenennaam et al. claims 21, 31, 55, 60, 68, 69, 73, 79 and 87 disclose transgenic plants with elevated levels of tocotrienol and that each claim of an issued patent enjoys a presumption of validity. Appellants note that Eenennaam et al. is a published application, not a patent, and that the claims cited by the Examiner do not teach plants with elevated levels of mixed tocotrienols. Claims 21, 31, 55, 60, 73 and 79 are directed towards plants and seeds with increased α -tocotrienol. Claims 68, 69 and 87 are directed towards plants and seeds with increased γ -tocotrienol. None of these claims are directed towards feeding an animal a diet comprised of a range of mixed tocotrienols.

Accordingly, Eenennaam et al. does not teach a method of improving the tissue quality of an animal, comprising feeding the animal a diet of mixed tocotrienols. In view of the differences between the claimed invention and the references of record, the claimed

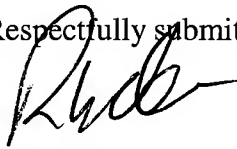
invention is not anticipated by Eenennaam et al. Therefore, the § 102(e) rejection of claims 1, 2, 13, 14-16, 20, 21 and 27-29 with respect to Eenennaam, et al. should be reversed.

IX. CONCLUSION

For the above-stated reasons, it is submitted that the claims are in a condition for allowability. The decision of the Examiner, therefore, should be reversed and the case allowed.

Please charge Deposit Account No. 26-0084 the amount of \$540.00 for this Appeal Brief. No other fees or extensions of time are believed to be due in connection with this appeal; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



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X. APPENDIX - CLAIMS

1. A method of improving the tissue quality of an animal, comprising feeding the animal a diet comprising at least 150 ppm mixed tocotrienols.
2. The method of claim 1 wherein the tissue is meat and the quality of the meat is measured by criteria selected from the group consisting of pH, improved color value, improved oxidative stability, and reduced purge.
12. The method of claim 1 wherein the animal is a ruminant.
13. The method of claim 12 wherein the animal is cattle.
14. The method of claim 1 wherein the diet comprising at least 150 ppm mixed tocotrienols comprises a cereal grain crop genetically modified to have elevated mixed tocotrienol levels.
15. The method of claim 14 wherein the cereal grain crop is corn.
16. The method of claim 1 wherein the diet comprising at least 150 ppm mixed tocotrienols comprises oil from a plant that has been genetically modified to have elevated mixed tocotrienol levels.
20. A method of improving the tissue quality of an animal, comprising feeding the animal a diet comprising 50 ppm to 500 ppm mixed tocotrienols.

21. The method of claim 20 wherein the tissue is meat and the quality of the meat is measured by criteria selected from the group consisting of increased pH, improved color value, improved oxidative stability and reduced purge.

27. The method of claim 20 wherein the diet comprising 50 ppm to 500 ppm mixed tocotrienols comprises a cereal grain crop genetically modified to have elevated mixed tocotrienol levels.

28. The method of claim 27 wherein the cereal grain crop is corn.

29. The method of claim 20 wherein the diet comprising 50 ppm to 500 ppm mixed tocotrienols comprises an oil from a plant that has been genetically modified to have elevated mixed tocotrienol levels.

XI. EVIDENCE APPENDIX

None

XII. RELATED PROCEEDING APPENDIX

None